Drugs recently approved or pending approval

BROVANA

The US Food and Drug Administration (FDA) has given approval to Sepracor, Inc. (Marlborough, MA) to market Brovana (arformoterol tartrate) inhalation solution for the long-term, twice-daily maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis, and emphysema (used by nebulization only). Brovana is the first long-acting β_2-agonist to be approved as an inhalation solution for use with a nebulizer. Brovana was evaluated in two 12-week multicenter, randomized, double-blind, placebo- and active-controlled, parallel-group trials involving 1456 adult patients (age range, 34–89 years) with COPD (mean forced expiratory volume in 1 sec [FEV_1], 1.3 L). Patients were randomized to Brovana 15 µg twice daily (n = 288), 25 µg twice daily (n = 292), 50 µg once daily (n = 293), placebo (n = 293), or salmeterol inhalation aerosol 42 µg twice daily (n = 290). The primary efficacy endpoint was the percent change in FEV_1 over 12 weeks. In both trials, Brovana 15 µg twice daily resulted in significantly greater postdose bronchodilation compared with placebo as measured by the primary efficacy endpoint. Brovana 25 µg twice daily and 50 µg once daily did not provide sufficient additional benefit. Brovana-treated patients demonstrated improvements in peak expiratory flow rates, supplemental ipratropium, and rescue albuterol use as compared with placebo. The most common adverse effects were pain, chest pain, back pain, and diarrhea.

NOXAFIL

The FDA has given approval to Schering Corporation (Kenilworth, NJ) to market Noxafil (posaconazole) for prophylaxis of invasive *Aspergillus* and *Candida* infections in patients (aged ≥ 13 years) who are at high risk of developing these infections due to being severely immunocompromised (eg, hematopoietic stem cell transplant [HSCT] recipients with graft versus host disease [GVHD], hematologic malignancies with prolonged neutropenia). Noxafil is the first antifungal agent approved for the prevention of invasive fungal infections (IFIs) caused by *Aspergillus* species. Noxafil was evaluated in 2 randomized controlled studies. Study 1 was a randomized, double-blind trial that compared Noxafil (200 mg 3 times/day) with fluconazole (400 mg once daily) as prophylaxis against IFIs in allogenic HSCT recipients with GVHD (N = 600). Patients were assessed at 7 days and 16 weeks postrandomization. Study 2 was a randomized, open-label study that compared Noxafil (200 mg 3 times/day) with fluconazole (400 mg once daily) or itraconazole (200 mg twice daily) as prophylaxis in neutropenic patients who were receiving cytotoxic chemotherapy for acute myelogenous leukemia or myelodysplastic syndrome (N = 602). Patients were assessed at 7 and 100 days postrandomization. In both studies, efficacy was evaluated using a composite endpoint of proven/probable IFIs, death, or treatment with systemic antifungal therapy. The clinical failure rate of Noxafil-treated patients was similar to fluconazole-treated patients in study 1, and clinical failure was lower for Noxafil-treated patients as compared with fluconazole- or itraconazole-treated patients in study 2. Both studies demonstrated substantially fewer breakthrough infections caused by *Aspergillus* species in Noxafil-treated patients as compared with fluconazole- or itraconazole-treated patients. The most common adverse effects were bilirubinemia, increased hepatic enzymes, hepatocellular damage, nausea, and vomiting.

VECTIBIX

Amgen Inc. (Thousand Oaks, CA) has been given FDA approval to market Vectibix (panitumumab) for the treatment of epidermal growth factor receptor (EGFR)–expressing metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens. The safety and efficacy of Vectibix were evaluated in an open-label, multinational, randomized controlled trial involving 463 patients with EGFR-expressing metastatic carcinoma of the colon or rectum. Patients were required to have progressed on or following treatment with a regimen containing a fluoropyrimidine, oxaliplatin, and irinotecan, which was confirmed by an independent review committee. Patients received either Vectibix 6 mg/kg once every 2 weeks plus best supportive care (BSC; n = 231) or BSC alone (n = 232) until investigator-determined disease progression. Once disease progression was confirmed, patients who received only BSC were eligible to receive Vectibix and were followed until disease progression was confirmed by the independent review committee. Vectibix-treated patients had a statistically significant prolongation in progression-free survival as compared with patients who received BSC alone (mean progression-free survival, 96 days versus 60 days, respectively). The most common adverse effects were skin rash, hypomagnesemia, paronychia, fatigue, abdominal pain, nausea, and diarrhea.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Tricia Faggioli, Hospital Physician, *125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.*

Copyright 2006 by Turner White Communications Inc., Wayne, PA. All rights reserved.